ISBT 128 Standard for Base Labels

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Table of Contents

1 Introduction 4
1.1 Purpose 4
1.2 Scope 4
1.3 Intended Audience 4
1.4 Normative Reference 4
1.5 Other Reference 4
1.6 Background 4
1.7 Changes in This Version 5
2 Blood and Cell Therapy Base Labels 6
2.1 Base Label on Standard Size Containers 6
2.2 Standard Base Label for Linear Bar Code Placement 6
2.3 Small Base Label for Linear Bar Code Placement 7
2.4 2-D Transition Base Label 9
2.5 2-D Base Labels 10
2.6 Additional Manufacturer Information 11

Tables

Table 1 Positioning Bar Codes on the Base Labels [RT020] 6
Table 2 Positioning Bar Codes on 50 mm by 75 mm Containers [RT021] 8

Figures

Figure 1 Placement and Nominal Size of Bar Codes on Base Label 7
Figure 2 Placement and Nominal Size of Bar Codes on a 50 mm by 75 mm Base Label 8
Figure 3 Example 2-D Symbol Placement on Transition Label 9
Figure 4 Example 2-D Symbol Placement on Smaller Transition Label 10
Figure 5 Base Label Examples with Only 2-D Symbol 11

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1 Introduction

1.1 Purpose

The purpose of this document is to provide specifications for base labels that carry ISBT 128 Data Structures.

1.2 Scope

This document applies to base labels of blood bags for blood and cellular therapy products. The ISBT 128 specifications provided in this document are limited to the dimensions and design of the base label. Specific requirements regarding the types of adhesives used are outside of the scope of the ISBT 128 Standard.

1.3 Intended Audience

The intended audience of this document is manufacturers of containers that are intended to hold MPHO products such as blood and cells.

1.4 Normative Reference

ISBT 128 Standard Technical Specification (ST-001)

ISO 3826-1:2019 Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers

1.5 Other Reference

ICCBBA Website (www.isbt128.org)

1.6 Background

While much of the ISBT 128 Standard is focused on the final labeling of Medical Products of Human Origin, there is a need to standardize the base labels that are applied to the empty containers prior to their use for MPHO. Standardizing the base label plays a role in how the standardized final label can be accommodated when overlayed onto the base label. Of particular importance are the dimensions of the base label. In some regulatory settings, the final label is not allowed to overlap the base label and come into direct contact with the container. Therefore, it is important that the base label dimensions are not exceeded by the final label dimensions.

Container manufacturers are primarily responsible for applying the base labels onto their containers. Each manufacturer may have their own set of local or national requirements for presenting information onto the label. The ISBT 128 Standard also has its own set of requirements for what type of information needs to be presented on the base label. Minimally, these requirements focus on key identifiers that are needed to facilitate

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traceability and recall efforts. Standardized placement of the ISBT 128 information helps to differentiate it from other information on the label.

Specifications on the standardized placement of linear bar codes on the base label were previously defined in the documents *ISBT 128 Standard Labeling of Blood Components* (ST-005) and *ISBT 128 Standard Labeling of Cellular Therapy Products* (ST-004).

1.7 Changes in This Version

The following table indicates the major changes between Version 1.0.0 and Version 1.0.1. Actual changes or additions to requirements of the ISBT 128 Standard are in bold print; changes to formatting or organization, or additional guidance, are in regular print.

	Version 1.0.0 Chapter, Section, Table, or Figure	Version 1.0.1 Chapter, Section, Table, or Figure	Change	Rationale
1.	1.4	1.4	Added hyperlink to document ST-001.	For consistency and to provide a quick link to access the referenced document.

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2 Blood and Cell Therapy Base Labels

2.1 Base Label on Standard Size Containers

Where the container is of sufficient size, the base label dimensions shall fall within the acceptable range of 98-102 mm W x 104-110 mm H.

It is recommended that the base label dimensions comply with ISO 3826-1. Therefore, the minimum width of 100 mm is recommended.

2.2 Standard Base Label for Linear Bar Code Placement

The base label should carry the two manufacturer's information bar codes: the Container Manufacturer and Catalog Number [017] bar code in the lower left quadrant and the Manufacturer's Lot Number [018] bar code in the lower right quadrant. The recommended position for these bar codes on the base label is indicated in Table 1.

Table 1 Positioning Bar Codes on the Base Labels [RT020]

Bar Code	Vertical Alignment	Horizontal Alignment
Container Manufacturer and Catalog Number [017]	9 mm ± 2mm from bottom of label*	Bar code right edge should be at 4 mm ± 2mm from right edge of Left Quadrant*
Container Lot Number [018]	9 mm ± 2mm from bottom of label*	Bar code left edge should be at 4 mm ± 2mm from left edge of Right Quadrant*

* Concatenation distances must also be maintained

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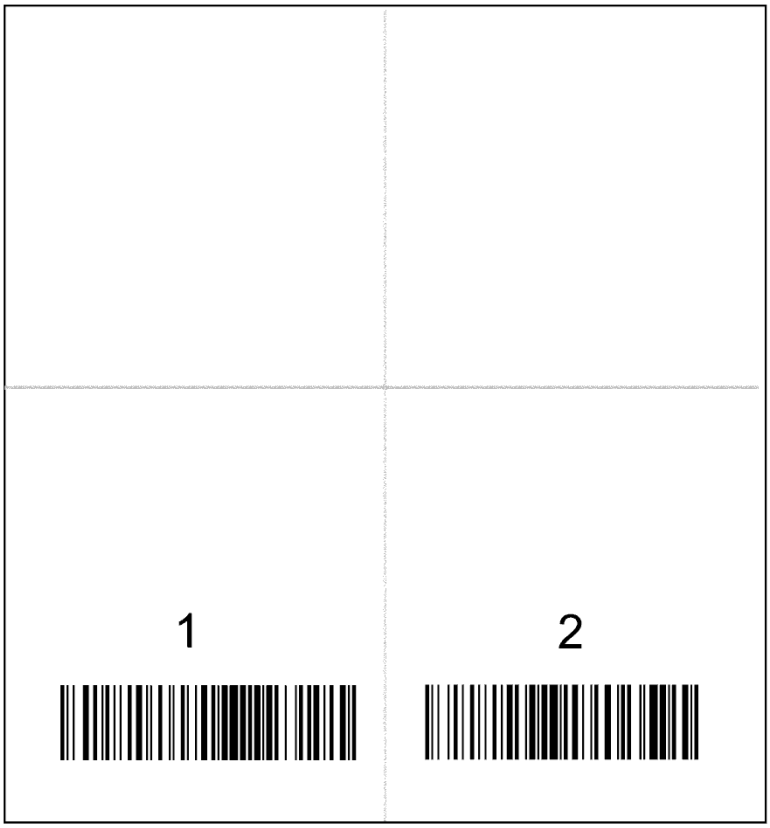
Figure 1 Placement and Nominal Size of Bar Codes on Base Label



Required Bar Codes
1 – Container Manufacturer and Catalog Number
2 – Container Lot Number

Gray lines are for reference only and should not be printed on the label

2.3 Small Base Label for Linear Bar Code Placement

The size of some containers does not allow a 100 mm x 106 mm base label. In designing smaller labels, the principles outlined in this chapter should be applied to the extent possible.

An alternative label design may be used if the container will accommodate a 50 mm x 75 mm label. The Container Manufacturer and Catalog Number [017] bar code shall be printed vertically in the upper half of the label and the Manufacturer's Lot Number [018] shall be printed vertically in the lower half of the label.

The recommended positions for these bar codes are indicated in Table 2, and is illustrated in Figure 2. This places the bar codes in an ideal position for concatenation.

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In order to accommodate the smaller size of the 50 mm x 75 mm label, and allow for concatenation of the bar codes, an X dimension as small as 0.17 mm may be used.

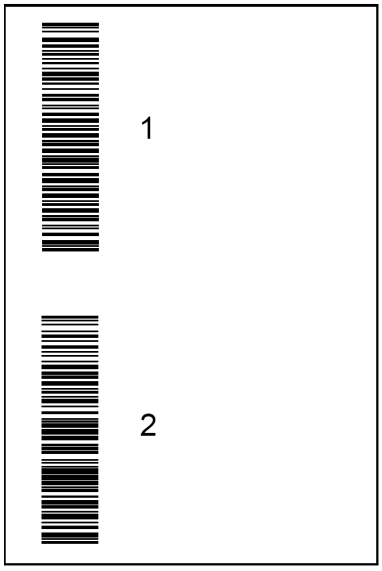
The bar code height may also be reduced to equal or greater than 15% of the bar code length (e.g., reduced to approximately 7 mm if the bar code is approximately 43 mm) in order to accommodate required text. Refer to *ISBT 128 Standard Technical Specification* (ST-001) for the standard bar code height.

Table 2 Positioning Bar Codes on 50 mm by 75 mm Containers [RT021]

Bar Code	From vertical center of label	From left side of label
Container manufacturer and catalog number	The right edge of the bar code is 4 mm ± 2mm above the vertical center of the label*	Lower edge of the bar code is 6 mm ± 2mm from the left side of the label*
Lot number	The left edge of the bar code is 4 mm ± 2mm below the vertical center of the label*	The lower edge of the bar code is 6 mm ± 2mm from the left side of the label*

* Concatenation distances must also be maintained

Figure 2 Placement and Nominal Size of Bar Codes on a 50 mm by 75 mm Base Label



1 – Container Manufacturer and Catalog Number
2 – Container Lot Number

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2.4 2-D Transition Base Label

It is recognized that a transition period may be needed where both linear bar codes and the 2-D Data Matrix symbol appear on the label before implementing the use of only 2-D. However, this may not always be the case.

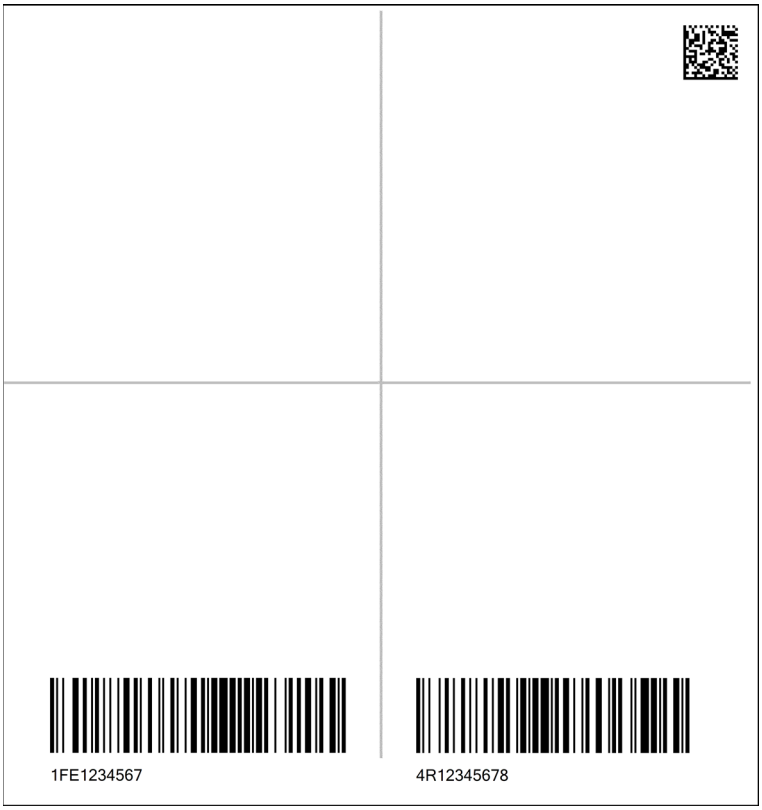
Based on the many different configurations and various types of information that a bag manufacturer may place on their base label, there will be no exact placement specified for the 2-D symbol.

If a blood bag manufacturer chooses to print an ISBT 128 2-D symbol on the base label, it shall appear in the upper right quadrant.

Existing requirements for quiet space and X-dimension shall be observed. Refer to the *ISBT 128 Technical Specification* (ST-001).

The example label below shows just one possible 2-D placement option within the upper right quadrant.

Figure 3 Example 2-D Symbol Placement on Transition Label



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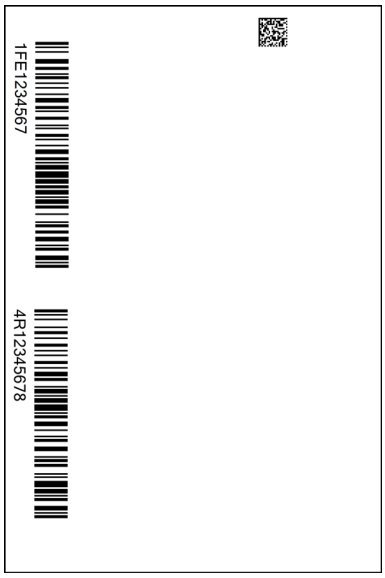
For smaller base labels, where the linear bar codes are printed vertically along the left edge, the 2-D symbol shall be placed towards the upper right region.
See example below for one option.

Figure 4 Example 2-D Symbol Placement on Smaller Transition Label



The 2-D symbol shall encode the ICCBBA-specified compound message 005 (refer to Reference Table RT017 found on the ICCBBA website) that contains Data Structure 017 (Container Manufacturer and Catalog Number) and Data Structure 018 (Container Lot Number).

The ISBT 128 Standard does not preclude the use of other non-ISBT 128 symbols on the base label. If the base label contains more than one 2-D symbol, the manufacturer shall clearly identify which one is the ISBT 128 Data Matrix symbol.

2.5 2-D Base Labels

Manufacturers may work with specific customers to fulfill contractual agreements to provide only the 2-D symbol with very little to no transition period.

If the 2-D symbol will be the only scannable ISBT 128 delivery mechanism on the base label, then the 2-D symbol shall still appear in the upper right quadrant. See examples below.

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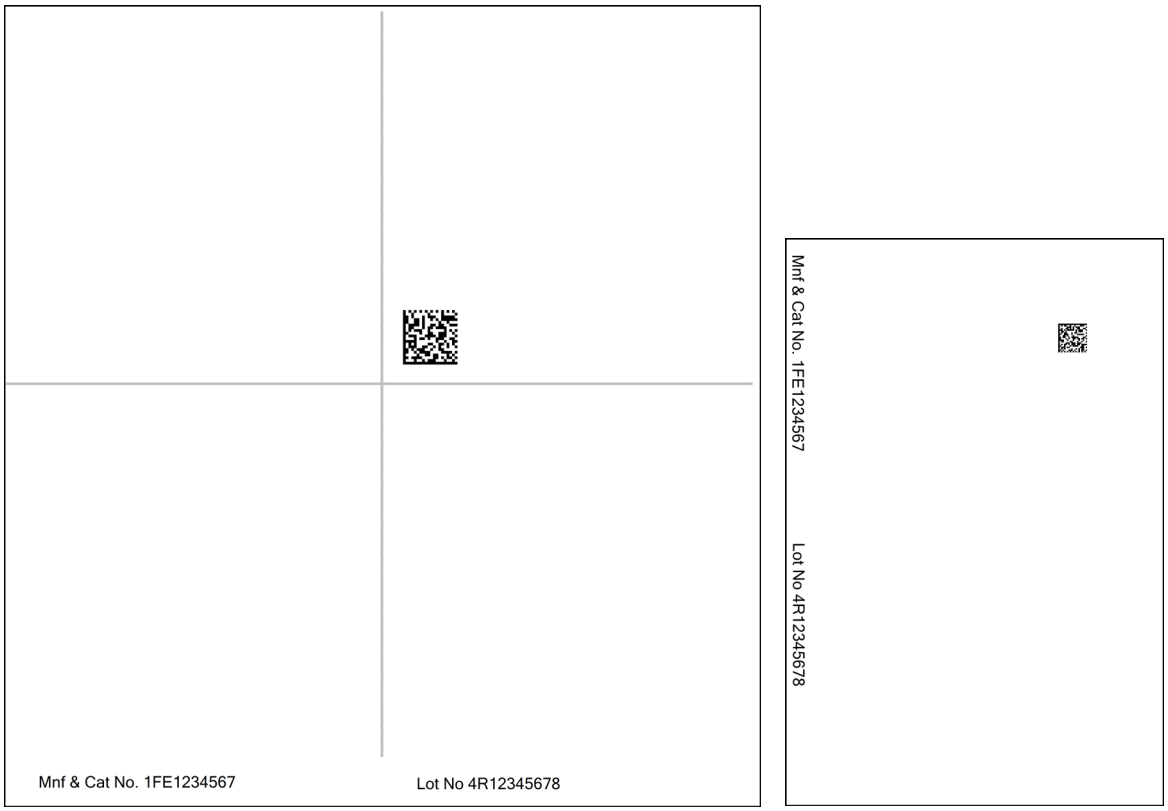
Figure 5 Base Label Examples with Only 2-D Symbol



2.6 Additional Manufacturer Information

Manufacturers may include additional information on their base labels such as:

- icons
- user friendly catalog numbers and lot numbers
- the intended use of the bag in text (e.g., For Platelet Storage)
- appropriate warnings (e.g., Not Suitable for Storage of Red Blood Cells or the number of days a platelet product can be stored within the container)

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END OF PUBLICATION

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These links are for internal document control and cannot be used externally:

ST-001 ISBT 128 Standard Technical Specification

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